Supreme Court, U.S.
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No. 92-___

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

JENNIFER STAMPS,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, that bars states from "establishing or continuing in effect" device requirements that are "different from, or in addition to" a requirement under the MDA, preempts all state-law damage claims against a manufacturer of a medical device approved for marketing by the Food and Drug Administration ("FDA") where:

> (1) there are no specific federal regulatory requirements for the device in question that coincide with petitioner's state law claims, and (2) the FDA's own view is that the MDA does not preempt damage claims.

PARTIES TO THE PROCEEDINGS

In addition to petitioner Jennifer Stamps and respondent Collagen Corporation, who appeared as appellant and appellee, respectively, in the court of appeals, the State of Texas, the Association of Trial Lawyers of America, the Health Industry Manufacturers Association, and the Product Liability Advisory Counsel, Inc. appeared as *amici curiae* in the court of appeals.

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JENNIFER STAMPS,
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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Fifth Circuit is reported at 984 F.2d 1416 (1993), and is reproduced in the appendix at 1a-15a. The unreported decision of the United States District Court for the Southern District of Texas is reproduced in the appendix at 16a-18a.

JURISDICTION

The judgment of the court of appeals was entered on February 19, 1993. Petitioner filed a timely petition for rehearing on March 5, 1993, which was denied by the court of appeals on March 19, 1993 (19a). This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to

a device intended for human use any requirement--

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

> **(1)** the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> **(2)** the requirement--
>
> > **(A)** is required by compelling local conditions, and
> >
> > **(B)** compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only

> when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT

This case presents the question of whether, under the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the Food and Drug Administration's decision to allow the marketing of a medical device insulates the manufacturer from all state-law damages liability. In 1988, petitioner Jennifer Stamps was administered respondent's medical devices, known as Zyderm and Zyplast, which were injected under petitioner's skin to remove skin deformities (2a-3a). Shortly after the injection, petitioner began to suffer from dermatomyositis/polymyositis ("DM/PM"), an autoimmune disease "in which an individual's immune system identifies one's own skin and muscle tissue as foreign and attacks them" (3a). Specifically, petitioner alleged that, within about a

month of receiving the injection, she was suffering from extreme pain and weakness in her muscle and joints, and esophageal insufficiency, causing her great difficulty in walking, among other disabling conditions. Original Petition, ¶ II.

Petitioner filed suit in Texas state court in 1990, alleging, among other things, that the medical devices were defectively designed and that respondent knew of the relationship between Zyderm and her illness but failed to warn her of that fact. *Id.* ¶¶ IV, V. She based her claims on negligent failure to warn, defective labeling, strict liability, and negligence *per se* under Texas common law (3a). Respondent removed the case to federal court based on diversity of citizenship.

Without addressing the merits, the district court and the court of appeals dismissed all of petitioner's claims on the ground that they were preempted by the MDA (15a, 18a). *See* 21 U.S.C. § 360k(a). This case presents the same legal questions as are before this Court in *King v. The Collagen Corporation*, No. 92-1979, filed on June 13, 1993, which was decided by the First Circuit about a month before the decision below.[1] Indeed, as the court of appeals below noted, the two cases concern the same manufacturer and medical device (7a), and counsel for both petitioners and respondent are the same in both cases.

Given the identity of the two cases, petitioner Stamps does not reiterate in full the arguments set forth in the petition in *King*, but asks only that this Court dispose of this petition in a manner consistent with *King*. Thus, if the Court grants certiorari in *King*, as we believe it should, the Court should either hold in abeyance this petition pending the disposition in *King*, or grant certiorari here and consolidate the two cases for plenary review. If certiorari is denied in *King*, then it should be denied here as well.

However, as fully described in the *King* petition, certiorari should not be denied because the issues presented here are of great importance to the medical-device industry, medical-device consumers, and to the Food and Drug Administration ("FDA"), whose regulations and other rulings counsel strongly against the

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[1] *King* was decided by the First Circuit on January 15, 1993, with rehearing denied on February 3, 1993, while the decision below was rendered by the Fifth Circuit on February 19, 1993, with rehearing denied on March 19, 1993.

decision here and in *King*.[2] As noted in the *King* petition, the FDA's former Chief Counsel has called that case "probably the single most important case to the medical-device industry in American history."[3] The fact that injured consumers living in the geographical area of two courts of appeals are now without any remedy against manufacturers of the most potentially injurious medical devices only reinforces the need for review by this Court.

CONCLUSION

The petition for a writ of certiorari should be disposed of in a manner consistent with the Court's disposition of the petition in *King v. The Collagen Corporation*, No. 92-1979 (filed June 13, 1993).

Respectfully submitted,

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[2] *See King* Petition at 14-15, 21-22, 24 & n.17.

[3] Edward Felsenthal & Lee Berton, *FDA Approval Shields Firms in Injury Suits*, Wall St. J., Jan. 21, 1993, at B1 (quoting Peter Hutt, former FDA Chief Counsel).

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

[FILED FEB 19, 1993]

No. 92-2084

JENNIFER STAMPS,

Plaintiff-Appellant,

VERSUS

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

Before GOLDBERG, SMITH, and EMILIO M. GARZA, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

Contending that she contracted a rare autoimmune disease from being injected with defendant Collagen Corporation's ("Collagen") products, Jennifer Stamps filed suit to recover damages in state court, alleging causes of action based upon defective design, inadequate warnings, and negligent failure to warn. Collagen timely removed and thereafter moved for summary judgment. The district court found all of Stamps's state law claims to be preempted by federal law and granted summary judgment. We affirm.

I.

A.

Zyderm and Zyplast are so-called Class III medical devices regulated under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360l, pursuant to which the Food and Drug Administration ("FDA") classifies all medical devices in one of three categories. See 21 U.S.C. § 360c. Class I devices generally pose little or no threat to public health and safety; tongue depressors are an example. Accordingly, Class I devices are subject only to general controls on manufacturing processes.

Class II items are more complex than Class I and include such devices as oxygen masks used in anesthesiology and tampons. These may be subject to recommendations, guidelines, post-marketing surveillance, the development of patient registries, and even the promulgation of specific performance standards, should the FDA deem them a sufficient health hazard as to require strict product specifications or warnings. See 21 U.S.C. § 360c(a)(B).

Class III devices, such as Zyderm, require premarket approval ("PMA"), which process permits the FDA to determine whether a proposed product provides "reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(C). Such devices are subject to the more stringent PMA process because they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

The PMA process requires a manufacturer to submit a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling. See 21 U.S.C. § 360e(c). The FDA refers each application to a panel of qualified experts that prepares a report and recommendation. Within six months, the FDA must either accept or reject the application. 21 U.S.C. § 360e(d).

B.

In March and April 1988, Stamps was injected with Zyderm and Zyplast, which contain processed bovine collagen that Collagen markets as an anti-wrinkle treatment for middle-aged women. A typical treatment consists of a series of injections

directly under the skin, the collagen then remaining to smooth out any wrinkles or deformities on the skin's surface.

Shortly after receiving her injections, Stamps began complaining of muscle and joint pains that subsequently were diagnosed as dermatomyositis/polymyositis ("DM/PM"). DM/PM is a relatively rare autoimmune disease in which an individual's immune system identifies one's own skin and muscle tissue as foreign and attacks them. Stamps claims that Collagen's products attached to her tissues and provoked an immune response that destroyed her body tissue.

II.

In granting summary judgment, the district court likened the instant case to Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989), in which we found a plaintiff's state-law-based failure-to-warn and labeling claims regarding a Class II medical device (tampons) to be preempted, although her defective construction and design claims survived. Reasoning that collagen implants are regulated under Class III, which requires FDA pre-market approval of not just labeling and packaging, but manufacturing methods as well, see, e.g., 21 C.F.R. §§ 814.20, 814.80, the court concluded that Stamps's claims are completely preempted.

Appellant Stamps disputes the district court's interpretation of the MDA and its application of Moore, contending that the MDA neither expressly nor impliedly preempts general state tort law and that Moore must be limited to the Class II regulatory context it describes. As a final matter, Stamps argues that even if we find Moore compelling precedent in the Class III context as well, the most it can be said to require is the preemption of her defective labeling and negligent failure-to-warn claims; her products liability, fraud, and negligence per se causes of action, as in Moore, should be reinstated.

III.

The question is whether the MDA preempts Stamps's state law claims. The Supremacy Clause of the Constitution invalidates state laws that "interfere with, or are contrary to" federal law, U.S. Const. art. VI, cl. 2. When "the field which Congress is

said to have preempted has been traditionally occupied by the States . . . 'we start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress.'" Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (citations omitted); see also Hillsborough County v. Automated Medical Lab., 471 U.S. 707, 715 (1985) (recognizing a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause"). Accordingly, "'[t]he purpose of Congress is the ultimate touchstone'" of preemption analysis. Malone v. White Motor Corp., 435 U.S. 497, 504 (1978) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).

Congress's intention to preempt may be either express or implied from the statutory text. Absent an express declaration, Congressional intent to preempt state law may be inferred only if state law actually conflicts with federal law, see Pacific Gas & Elec. Co. v. Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983), or where the scheme of federal legislation is so comprehensive "'as to make reasonable the inference that Congress left no room for the States to supplement it.'" Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting Rice, 331 U.S. at 230).

IV.

A.

The Supreme Court's most recent and authoritative treatment of preemption doctrine is Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). In Cipollone, a plurality held that a lung cancer victim's suit against cigarette manufacturers alleging breach of warranty, failure to warn, fraudulent misrepresentation, and conspiracy to deprive the public of medical information regarding smoking was not preempted by the 1965 Federal Cigarette Labeling and Advertising Act; certain of her failure to warn and fraudulent misrepresentation claims were, however, preempted by the language added by Congress to the Public Health Cigarette Smoking Act of 1969. Id. at 2625.

In Cipollone, the Court relied exclusively upon the express language of the statutory provision regarding preemption. Reasoning that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted," the Court concluded,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation....Therefore, we need only identify the domain expressly pre-empted by [the statute].

112 S. Ct. at 2618 (citations omitted). See also id. at 2625 (Blackmun, J., concurring) (same).

The MDA was enacted in 1976 as an amendment to the Federal Food, Drug and Cosmetic Act of 1938. Like the Public Health Cigarette Smoking Act addressed in Cipollone, it contains a provision expressly addressing its intended preemptive scope:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (Supp. 1992).

B.

Applying Cipollone, we reject, at the outset, Collagen's contention that we may resort to the doctrine of implied preemption to uphold the district court. The existence in the MDA of an express preemption provision precludes any such reliance.

C.

We likewise must reject Stamps's argument that Congress did not intend to preempt state tort law remedies when it enacted the MDA. Section 360k(a) speaks broadly: Any state requirement "different from, or in addition to," federal law is preempted.

Moreover, Stamps's contention that the MDA does not preempt common law tort actions is necessarily foreclosed by Moore. Implicit in our holding that certain of Moore's state law claims were preempted by the applicable FDA Class II regulations is the conclusion that Congress intended the preemption of state tort liability where such liability effectively creates a requirement "different from, or in addition to" specific federal requirements. Congress, of course, has the power so to displace state tort law remedies. See, e.g., Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 331 (1981) (state common law may be preempted by federal law).

This result is fortified not merely by Moore's compatibility with the analysis pursued in Cipollone but also by the Court's determination that the language of the statute at issue there, preempting any state "requirement or prohibition," "sweeps broadly and suggests no distinction between positive enactments and common law...." Cipollone, 112 S. Ct. at 2620. It would be anomalous to interpret the MDA differently from the Public Health Cigarette Smoking Act solely on the basis that while they both employ "requirement," the MDA omits "prohibition."[1] Thus, Moore correctly decided this issue; section 360k(a) also "sweeps broadly" and encompasses common law tort actions within its preemptive scope. See also Morales v. Trans World Airlines, Inc., 112 S. Ct. 2031, 2037 (1992) (finding state common law actions "relating to" airline advertising preempted by Airline Deregulation Act of 1978).

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[1] Indeed, the FDA regulation that parallels § 360k(a), 21 C.F.R. § 808.1(b), extends the "any requirement" language of that section to any medical device standard "having the force and effect of law (whether established by statute, ordinance, regulation, or court decision) . . . . " (Emphasis added.)

D.

Returning to Cipollone's admonition that our inquiry be guided solely by the express language of the statute's preemption provision, we glean from section 360k(a) the following analysis: A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA.[2] See also King v. Collagen Corp., 1993 U.S. App. LEXIS 432, at *12-*13 (1st Cir. Jan. 15, 1993) (applying similar test to identical product).

By this test, we find that our decision in Moore logically extends to the FDA Class III regulatory context and that Stamps's claims may be preempted under the MDA. Simply put, Texas tort liability, following Cipollone, would constitute a requirement either different from, or in addition to, a requirement -- the Class III PMA process - that the MDA has made applicable to Zyderm and Zyplast. The second part of the analysis, involving as it does the "relates to" language of section 360k(a)(2) recently given a sweeping interpretation by the Supreme Court in Morales, 112 S. Ct. at 2037-38, is even simpler than the first. In the context of this case, Stamps's state law claims undoubtedly "relate to" either

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[2] The FDA's gloss on § 360k(a) poses essentially the same test:

> (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] of the act because they are not "requirements applicable to a device" within the meaning of section [360k(a)] of the act.

21 C.F.R. § 808.1(d). As with administrative agencies generally, the FDA's construction of the statute is entitled to "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945). Neither party contests the validity of the FDA's regulations pursuant to the MDA.

the safety or effectiveness of Zyderm and Zyplast, or to some other matter included in the PMA requirements applicable to She products.[3]

V.

Because the MDA, like the statute at issue in Cipollone, fails to "indicate that any familiar subdivision of common law claims is or is not pre-empted," Cipollone, 112 S. Ct. at 2621, we must pursue the "straightforward" inquiry commended to us by the Supreme Court: "[W]e ask whether the legal duty that is the predicate of the common law damages action constitutes" a requirement relating to the safety or effectiveness of Zyderm and Zyplast or to any other matter included in a requirement made applicable to it by the MDA. Id.

A.

We need not conduct a categorical inquiry into each cause of action pursued by the plaintiff, as did the Court in Cipollone, as Moore tells us that Stamps's inadequate labeling (paragraph IV of the original petition) and failure to warn (paragraph V) allegations are preempted by the MDA. The Class III regulatory structure, no less than that of Class II, involves the FDA in considerable oversight regarding proposed package labeling of a device.[4] Nor can Stamps's third cause of action (paragraph VI), based upon the defective design and manufacture of Collagen's products, survive

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[3] Applying the language of § 808.1(d), see supra note 2, yields the same result: The PMA process constitutes a "specific requirement[] applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

[4] See 21 U.S.C. § 360e(c)(1)(F) (requiring PMA application to contain samples of device's proposed labeling); 21 C.F.R. § 814.20(b)(10), (e) (same); see also 21 U.S.C. § 360e(d)(2)(A) -(B),(D) (requiring denial of PMA application for insufficient showing that the device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," or if the proposed labeling is false or misleading in any particular).

preemption, as the Class III PMA process includes FDA scrutiny and approval of these particular aspects of a device.[5]

B.

Stamps's claim that even if preemption applies to the Class III context, the MDA preempts state law only to the extent that the

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[5] See 21 U.S.C. § 360e(c)(1)(B)-(C) (requiring, in PMA application, statements and descriptions of the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device); id. § 360e(d)(2)(C) (requiring denial of application where "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title..."). See also 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.").

Moreover, § 360j(f)'s "[g]ood manufacturing practice requirements" impose further requirements upon the manufacture of Class III devices, leaving us with little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture, in the form of common law products liability duties.

Lastly, we note that we have not analyzed Stamps's fraud-based cause of action in accordance with Cipollone because we are convinced that her original petition contains no adequate averment of fraud. Although the petition does state in paragraph V that "Defendant engaged in an active campaign to suppress the facts, blame the adverse reactions on some other cause, and prevent discovery of the risks associated with its products," this sentence comes sandwiched between allegations of negligence in a paragraph that concludes only that "Defendant's conduct was negligent and was the proximate cause of Plaintiff's damages." Such an allegation of fraud would not suffice under Fed. R. Civ. P. 9(b); and while Stamps is technically correct that the burden lies with the defendant to request a more definite statement under Fed. R. Civ. P. 12(e) when a pleading or allegation is too vague or ambiguous to admit of a response, we do not believe such was the case here. Paragraph V is not vague or ambiguous; it reads quite plainly as an allegation of negligence. Albeit liberal with respect to the formalities, notice pleading is yet to be distinguished from reading tea leaves. To require Collagen to move for a more definite statement in order to determine whether, when Stamps pled negligence, she in fact meant fraud, would go far towards erasing that distinction.

state mandates a similar PMA process, presents a close question. In Larsen v. Pacesetter Sys., 837 P.2d 1273, 1282 (Haw. 1992), for example, the court has found that an implant patient's claims arising from the recall of a "substantially equivalent" Class III pacemaker were not preempted by the MDA, noting that "the statutes and regulations governing premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis under [21 C.F.R.] § 808.1(b)."[6] On this subject, the FDA has stated,

> Like all other medical device requirements, different or additional State and local [PMA] requirements are preempted when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act.

43 Fed. Reg. 13,664 (1978) (emphasis added).

This passage might be construed exclusively -- to the effect that only different or additional state PMA processes are preempted when the FDA has classified a device under Class III. We believe, instead, that the emphasized language above - added to the fact that the passage was written in response to public comments seeking clarification from the FDA as to "whether or when State and local

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[6] Larsen is distinguishable from the instant case in that it involved a device that passed through a less stringent Class III review process by virtue of its being "substantially equivalent" to devices already allowed to be marketed. As the court stated, "Although a determination of substantial equivalence involves a review by FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness." Larsen, 837 P.2d at 1282 (citing H.R. Rep. No. 8081, 101st Cong., 2d Sess. 14, reprinted in 1990 U.S.C.C.A.N. 6305, 6307; 21 C.F.R. § 807.97 (FDA's acceptance of claim of substantial equivalence does not denote official approval of the device)).

The instant devices are not "substantially equivalent" to marketable devices rather, they have been subjected to the full rigor of the PMA process. While we do not rely upon this ground, one could argue that 21 C.F.R. § 807.97's explicit statement that the FDA does not officially approve "substantially equivalent" devices creates at least the presumption -- by way of the doctrine expressio unius est exclusio alterius -- that the FDA does officially approve those products it scrutinizes through the regular Class III PMA process. Such official approval, of course, strongly would imply that federal preemption is present.

[PMA] requirements are preempted," id. - demonstrates that the better reading is that PMA processes are preempted in addition to any other state requirements relating to safety or effectiveness or any other MDA requirement established for the device.[7]

We believe the literal language of the statute compels this result: State requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the device under the MDA. Zyderm and Zyplast, it is undisputed, are required by the MDA to undergo the FDA's stringent PMA process. State tort causes of action -- to the extent they relate to safety, effectiveness, or other MDA requirements -- constitute requirements "different from, or in addition to the Class III process; they are, therefore, preempted."[8]

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[7] See Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.), cert. denied, 113 S. Ct. 327 (1992) (finding that MDA Class III devices developed under the FDA "Investigational Device Exemption" ("IDE") regulations are preempted from state tort law liability; although IDE regulations "do not specify the safe and effective design [,] they specify the procedures for determining whether the experimental design is safe and effective" and thus "are requirements relating to safety and effectiveness and they can therefore have preemptive effect"). To our knowledge, Slater and King are the only decisions by federal courts of appeals to have reached the preemptive scope of the MDA's Class III regulations, and both have reached conclusions consistent with our analysis herein. Inasmuch as we have previously determined in Moore that preemption applies in the MDA Class II sphere, extension of that holding to Class III regulations comports with logic and our understanding of the MDA regulatory scheme. Moreover, although we do not need to consult legislative history to decide this issue, we note that Senator Kennedy stated, when he introduced the MDA, that "[t]he most hazardous devices . . . would require full premarket testing and clearance before they are allowed on the market. Premarket clearance represents the highest degree of regulatory control...." 121 Cong. Rec. 10,688 (1975) (emphasis added); see also King, 1993 U.S. App. LEXIS 432, at *22- *28 (Aldrich and Campbell, JJ., concurring) (finding intent of Congress in enacting MDA was to provide maximum of protection available to medical device users).

[8] Nor does the seemingly more restrictive language of § 808.1(d) compel a different result. That section provides that state and local requirements are preempted "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act..." (emphasis added).

C.

Stamps also argues that Collagen's ability to strengthen the contraindications in its packaging and labeling proves that it could *comply with* both state tort law and the federal statute. In essence, Stamps argues that the MDA forms only the floor of regulation; the states are free to construct a regulatory ceiling.

We agree with Stamps that, under the Class III regulatory framework, Collagen could have strengthened its warning labels without first obtaining prior FDA approval. The "Conditions of Approval" issued with respect to Zyderm, for example, provide,

> Changes in labeling, manufacturing, sterilization, packaging, or performance of design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor prior to the receipt of a written FDA approval of the supplemental PMA....
>
> Specific examples of changes permitted are:
>
> (1) addition of warnings, contraindications, or side effects....

See also 21 C.F.R. § 814.39(d)(2)(i) (permitting without prior FDA approval "[l]abeling changes that add or strengthen a contraindication, warning, precaution or information about an adverse reaction.").

We cannot agree, however, with the conclusion Stamps draws from this -- that the lack of direct conflict between the state and federal regulations compels a finding of no preemption. While we are aware that the court in Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1540-43 (D.C. Cir.), cert. denied, 469 U.S. 1062

Stamps apparently reads out the latter half of this clause and points to the fact that the FDA premarket approval process is not a "specific counterpart regulation" to state tort law. We disagree with this interpretation and need look no further than the second half of the quoted clause. It is plain that § 808.1(d) poses the same test as the statute: When there exists a specific requirement applicable to a particular device under the act -- such as the MDA's PMA requirement for Zyderm and Zyplast -- additional or different state laws are preempted.

(1984), interpreting the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") similar express preemption provision, found no preemption where there was no direct conflict between the state and federal regulation, we do not believe the analysis therein applied can be said to have survived Cipollone, and was directly refuted in Morales. See Morales, 112 S. Ct. at 2038 (rejecting contention that express preemption is inappropriate where state and federal law are consistent).

In Ferebee, the court rejected Chevron's contention that FIFRA's express preemption provision, 7 U.S.C. § 136v(b), which said that states "shall not impose or continue in effect any requirements for labeling...in addition to or different from those required under this subchapter," required a holding of preemption of state tort liability. Instead, the court noted that Congress, although explicitly preempting state labeling "requirements," had not stated its intention to preempt state damages actions. 736 F.2d at 1542. Yet in the statute at issue in Cipollone, Congress had not expressly declared its intent to preempt state damages actions, and the Court nevertheless found them preempted, at least in part. Thus, no such "plain statement" of congressional intent as Ferebee contemplated is required. Moreover, we reiterate our belief that no sound distinction can be drawn between the "no requirement or prohibition" language found dispositive in Cipollone and the express preemption of "any requirement" contained in the FIFRA and the MDA.[9]

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[9] Lastly, to the extent Ferebee can be read to import a direct conflict requirement into express preemption analysis, it runs afoul of Cipollone, where the Court stated, 112 S. Ct. at 2618, that the language of the express preemption provision alone must guide the preemption inquiry. Direct conflict, moreover, is more appropriately considered as an aspect of implied preemption analysis, particularly of that version that applies where "compliance with both federal and state regulations is a physical impossibility." See Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 142-43 (1963); Osburn v. Anchor Lab., 825 F.2d 908, 912-13 (5th Cir. 1987), cert. denied, 485 U.S. 1009 (1989) (finding no implied preemption in FDA label PMA process for new animal drugs where FDA regulations permitted manufacturer to strengthen label warnings without prior approval).

As Cipollone has clarified, resort to implied preemption analysis is inappropriate where the statute specifies the scope of its intended preemptive effect. Lastly, the MDA is different from FIFRA, although it incorporates a

D.

Finally, we acknowledge that our reading of the MDA effectively denies Stamps access to state law damages actions as a remedy for her injuries. Stamps cites Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984), for the proposition that there is a strong presumption against preemption of state law remedies where no federal remedy exists. Like Stamps's direct conflict argument, however, this too is more appropriately addressed in the context of implied preemption.[10] That is to say, where Congress has expressly preempted state common law damages actions, as in Cipollone and the MDA, its failure to provide a federal remedy will not defeat its intent to preempt state law.[11]

VI.

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similar express preemption provision. And as regards the preemptive scope of the MDA, the FDA has stated,

> Congress has expressly declared that the Federal Food, Drug & Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption, therefore, does not apply....Under Section [360k(a)] of the act, preemption is not restricted to State requirements that directly conflict with Federal law....

45 Fed. Reg. 67326, 67328 (1980).

[10] See Silkwood, 464 U.S. at 256 (rejecting suggestion that "there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law," but refusing to recognize any such preemption in that case based upon implied "conflict" or "frustration" preemption); Abbott by Abbott v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), cert. denied, 488 U.S. 908 (1988) (applying unavailability of federal remedy presumption in impled preemption context).

[11] See Lee v. E.I. DuPont de Nemours & Co., 894 F.2d 755, 757 (5th Cir. 1990) (ERISA's express preemption provision preempts state tort law despite unavailability of federal remedy); see also Slater, 961 F.2d at 1333 ("It would be a mistake to conclude that preemption in these circumstances leaves the consuming public remediless, at least if we have concern for economic substance rather than legal formality and do not suppose that the only 'remedies'. . . are those that the law provides.").

In conclusion, the district court did not err in finding Stamps's state law claims completely preempted by section 360k(a). The summary judgment is AFFIRMED.

IN THE UNITED STATE DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JENNIFER STAMPS, Plaintiff,	)	[ENTERED OCT 16, 1991]
v.	)	CIVIL ACTION NO. H-90-2242
COLLAGEN CORPORATION Defendant	)	

MEMORANDUM OPINION

This case is before the Court on defendant's motion for summary judgment. Plaintiff alleges in her complaint[1] that she was injected with implants manufactured by defendant, that these implants were defective as manufactured, that defendant failed to provide adequate labeling or other warning of the defects, and that use of the allegedly defective implants caused her injury. Defendant asserts that plaintiff's claims are preempted by the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c, et seq., under which defendant's devices are strictly regulated. Defendant has submitted competent documentary evidence, authenticated by proper affidavit, in support of its motion for summary judgment, the parties have submitted briefs, and the motion is ripe for decision.

Preemption, which is based on the Supremacy Clause of the United States Constitution, "encompasses both federal statutes themselves s and federal regulations that are properly adopted." City of New York v. Federal Communications Comm., 486 U.S. 57 (1988). Absent clear language to the contrary, there is a presumption against preemption in matter regarding health and

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[1] Plaintiff's first motion for leave to file an amended complaint was subsequently withdrawn by plaintiff. Plaintiff's second motion for leave to file an amended complaint was not filed until after the discovery deadline and has been denied, with certain limited exceptions not relevant to the motion for summary judgment, as untimely.

safety. Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713 (1985).

Section 360k(a) of the MDA expressly provides that no state or political subdivision of a state may establish a safety or effectiveness requirement for a device subject to the provisions of the MDA which is different from or in addition to any requirement applicable under the MDA. The Food and Drug Administration (FDA) has promulgated regulations[2] which define "requirement" to include court decisions. 21 C.F.R. § 808.1(b). The FDA regulations also establish that state requirements are preempted where 'the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . ." 21 C.F.R. § 808.1(d).

It is undisputed that the devices used by plaintiff are subject to the MDA. The devices were classified by the FDA as Class III medical devices and, as a result, required FDA "premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). Pursuant to 21 U.S.C. § 360e(c), defendant was required to provide comprehensive information to the FDA, including information regarding design, manufacturing methods, proposed packaging and labeling, and data from premarketing laboratory tests and clinical investigations. Following extensive review, the FDA issued an approval order for the devices and the proposed labeling and thereby authorized the devices for marketing in strict compliance with the approval. Under federal law, approved Class III devices may not be manufactured, packaged or labeled in a manner different from the approval order. 21 C.F.R. § 814.80. Plaintiff's evidence that the FDA seized certain Collagen products which omitted language recently required for the new package inserts is a clear indication of the applicability of the regulations and the strength with which they are enforced by the agency.

The United States Court of Appeals for the Fifth Circuit, citing the FDA regulations discussed above, has held that state law claims are preempted where the FDA "has established specific counterpart regulations or there are other specific requirements

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[2] Plaintiff has neither asserted not [sic] presented evidence that the FDA regulations discussed herein were not properly adopted.

applicable to a particular device under the act. . ." Moore v. Kimberly-Clark Corp., 867 F.2d 243, 245 (5th Cir. 1989), quoting 21 C.F.R. § 801.1(d). Plaintiff attempts to avoid summary judgment by noting that defendant has not identified "specific counterpart regulations" governing the devices at issue. The regulation and the Moore case, however, require either specific counterpart regulations or other specific requirements applicable to a particular device. In this case it is clear that the FDA has established specific requirements applicable to the Collagen devices. The detailed requirements are set forth in the approval order and cannot be varied without FDA consent. Nor can the requirements be varied by state law or court decision. 21 U.S.C. § 360k(a). See also Moore, 867 F.2d at 244.

The Court recognizes that in Moore the device at issue had been classified by the FDA as a Class II medical device. The FDA regulates labeling of Class II devices, but does not have regulations dealing with their construction or design and does not require premarket approval. As a result, the Fifth Circuit held that plaintiff's warning and labeling claims were preempted, while her claims for defective construction and design were not. In the case at bar, however, the subject implants are Class III medical devices which require premarket approval as to manufacturing methods, labeling, packaging, etc. Consequently, the preemptive effect of the MDA would also reach plaintiff's claim for defective manufacture and design. See Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653, 656 (D.S.C. 1988).

Because the implants at issue in this case are subject to specific requirements under the MDA regarding manufacture, packaging and labeling, plaintiff's claims regarding defective manufacture, labeling and warning are preempted. As a result, defendant's motion for summary judgment must be granted. An appropriate final judgment and order consistent with this memorandum opinion shall be signed this day.

SIGNED this 11th day of October, 1991.

/s/ James DeAnda
Chief Judge
United States District Court

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 92-2084

JENNIFER STAMPS,

Plaintiff-Appellant,

VERSUS

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

ON PETITION FOR REHEARING

(MARCH 19, 1993)

Before GOLDBERG, SMITH, and EMILIO M. GARZA, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in above entitled and numbered case be and the same is hereby DENIED.

ENTERED FOR THE COURT:

/s/ Jerry E. Smith
United States Circuit Judge